

**CIVIL ACTION NO. 5:08-CV-00464-H**

Defendant.

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Request for *Ex Parte* Reexamination of U.S. Patent 6,566,052, Exhibit C. Talecris seeks a stay of this litigation pending completion of those reexaminations and related appeals.

## **STATEMENT OF FACTS**

### **I. The *Ex Parte* Reexamination Process.**

In 1980, Congress created the *ex parte* reexamination process. *See generally* 35 U.S.C. §§ 301-07. The purpose of this process was to “permit any party to petition the Patent Office to review the efficacy of a patent, subsequent to its issuance, on the basis of new information about preexisting technology which may have escaped review at the time of the initial examination of the patent application.” H.R. Rep. No. 96-1307, at 4 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6463. Congress expressed its intent that “[r]eexamination will permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation.” *Id.*

“[B]y allowing reexamination in limited circumstances, Congress wanted to reinforce confidence in patents by providing a body having expertise to settle validity disputes more quickly and cheaply than would litigation.” *In re Hiniker Co.*, 150 F.3d 1362, 1367 (Fed. Cir. 1998). The validity issues that arise in a reexamination proceeding are the same as those that arise in litigation, although the patent applicant has the ability to amend the claims at the PTO during a reexamination, unlike in a district court, which must take the claims as it finds them. *See* 35 U.S.C. § 305.

Talecris’s reexamination requests will almost certainly result in the commencement of reexamination proceedings in the PTO: the PTO has granted 8,467 out of 9,219 requests for *ex parte* reexamination since July 1, 1981, when the *ex parte* reexamination process was initiated, or 92% of such requests. U.S. Patent and Trademark Office, *Ex Parte* Reexamination Filing Data - Sept. 30, 2008, at 1, *available at* <http://www.uspto.gov/web/>

patents/documents/ex\_parte.pdf. Moreover, the reexamination proceedings will likely result in changes to the claims: of the 6,457 *ex parte* reexaminations resolved by the PTO, 4,833, or 75%, resulted in all of the claims of the reexamined patent being canceled or in changes to the claims. *Id.* at 2.

## **II. The Patents-in-Suit and Related Patent Applications.**

The PTO issued the patents-in-suit without considering whether Phatarfod barred their patentability.<sup>2</sup> The PTO discovered Phatarfod only after the patents-in-suit issued, and it cited Phatarfod as the basis for rejections of claims in pending U.S. Application Nos. 10/442,780 (the “’780 application”) and 11/374,484 (the “’484 application”). *See* June 28, 2007, Office Action for ’780 Application, Exhibit D, at 6-11; June 5, 2007, Office Action for ’484 Application, Exhibit E, at 12-15. The ’484 and ’780 applications are related to each other and to all three of the patents-in-suit: the ’484 application is a division of the ’780 application, which is a division of the application leading to the ’052 patent, which was a division of the application leading to the ’563 patent, which was a division of the application leading to the ’222 patent. Baxter has not overcome the rejections by the PTO of the claims in the ’780 and ’484 applications.

In those same Office Actions, the PTO also rejected the pending claims for nonstatutory obviousness-type double patenting over the patents-in-suit. *See* June 28, 2007, Office Action for ’780 Application, Exhibit D, at 2-5; June 5, 2007, Office Action for ’484 Application, Exhibit E, at 2-11. As described in Section 804 of the PTO’s Manual of Patent

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<sup>2</sup> Each of the patents-in-suit lists “References Cited” by either the PTO or the patent applicants on the first page of the patents. (The lists for the ’222 and ’563 patents are continued on the second page.) None of the patents-in-suit includes Phatarfod in those lists. Copies of the patents-in-suit are attached to the Complaint as Exhibits A (’222 patent), B (’563 patent), and C (’052 patent).

Examining Procedure (“MPEP”), a rejection for nonstatutory double patenting “is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinguishing from claims in a first patent.” MPEP § 804, Exhibit F, at 800-11 to -12. Thus, with these rejections, the PTO determined that claims of the ’780 and ’484 applications were essentially the same for patentability purposes as the claims of the patents-in-suit. As a result of this determination, the rejections of the claims over Phatarfod in the ’780 and ’484 applications should also apply to the patents-in-suit. Accordingly, Talecris filed the reexamination requests. As shown in those requests, all of the claims of the patents-in-suit are invalid over Phatarfod and other prior art references. *See* Request for *Ex Parte* Reexamination of U.S. Patent 5,780,222, Exhibit A; Request for *Ex Parte* Reexamination of U.S. Patent 6,063,563, Exhibit B; Request for *Ex Parte* Reexamination of U.S. Patent 6,566,052, Exhibit C.

### **ARGUMENT**

Stays pending reexamination are the norm. In creating the reexamination mechanism, Congress intended that courts liberally use their discretion to stay proceedings pending reexamination:

The Bill does not provide for a stay of court proceedings. It is believed by the Committee that stay provisions are unnecessary in that such power already resides with the court to prevent costly pretrial maneuvering which attempts to circumvent the reexamination procedure. It is anticipated that these measures provide a useful and necessary alternative for challengers and for patent owners to test the validity of United States patents in an efficient and relatively inexpensive manner.

H.R. Rep. No. 96-1307, at 4, *reprinted in* 1980 U.S.C.C.A.N. at 6463 (emphasis added). Thus, “[c]ourts frequently note that ‘[t]he legislative history surrounding the establishment of the reexamination proceeding evinces congressional approval of district courts liberally granting stays.’” *eSoft, Inc. v. Blue Coat Sys., Inc.*, 505 F. Supp. 2d 784, 786 (D. Colo. 2007) (*quoting*

*Robert H. Harris Co. v. Metal Mfg. Co.*, 19 U.S.P.Q.2d 1786, 1788 (E.D. Ark. 1991)) (first alteration added).

As a result, courts routinely grant stays pending reexamination. *See, e.g., Graham-White Mfg. Co. v. Ell-Con Nat., Inc.*, 2006 WL 2716439, Exhibit G, at \*2 (D.S.C. Sept. 22, 2006) (“District courts routinely grant a stay of proceedings pending reexamination, recognizing the many benefits and advantages that a stay provides.”). The liberal policy in favor of staying litigation pending reexamination “exists in large part because of the ‘simplification of litigation that might result from the cancellation, clarification, or limitation of claims, and, even if the reexamination did not lead to claim amendment or cancellation, it could still provide valuable analysis to the district court.’” *Cima Labs, Inc. v. Actavis Group hf*, 2007 WL 1672229, Exhibit H, at \*9 (D.N.J. June 7, 2007) (quoting *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1428 (Fed. Cir. 1988)). Indeed, this Court has noted and applied the “liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissuance proceedings.” *Cornerstone BioPharma, Inc. v. Vision Pharma, LLC*, 5:07-CV-00389-F, Exhibit I, at 2 (E.D.N.C. Feb. 15, 2008) (quoting *ASCII Corp. v. STD Entertainment*, 844 F. Supp. 1378, 1381 (N.D. Cal. 1994)).

This Court considers three factors in determining whether it should grant a stay:

(1) the stage of the litigation, including whether discovery is or will be almost completed and whether the matter has been scheduled for trial; (2) whether a stay will unduly prejudice or tactically disadvantage the nonmoving party; and, (3) whether a stay will simplify the issues in question and streamline the trial, thereby reducing the burden of litigation on the parties and on the court.

*Id.*; accord *eSoft*, 505 F. Supp. 2d at 787 (applying a similar four-factor test: “(1) whether a stay will simplify the issues in question and streamline the trial; (2) whether discovery is complete and whether a trial date has been set; (3) whether a stay would unduly prejudice the nonmoving

party or present a clear tactical advantage for the moving party; and (4) whether a stay will reduce the burden of litigation on the parties and on the court,” and noting that “[c]ourts frequently collapse the first and fourth factors”).

All factors counsel in favor of a stay here. First, the litigation is in its very early stages. Discovery has not yet begun, and the matter has not been scheduled for trial; indeed, Talecris only recently filed its Answer and Counterclaims, and the Court has not yet held a Status Conference or entered a Scheduling Order. As in *Cornerstone*,<sup>3</sup> “[t]hese factors confirm that this case is still in the early stages of litigation and that the parties have not invested any substantial expense therein. Therefore, the stage of litigation is not a deterrent, but rather a factor weighing in favor of the requested stay.” 5:07-CV-00389-F, Exhibit I, at 3; *see also ASCII*, 844 F. Supp. at 1381 (granting a stay because “the parties are in the initial stages of the lawsuit and have undertaken little or no discovery”).

Second, a stay will not unduly prejudice Plaintiffs. Patent owners often oppose stays on the ground that a reexamination proceeding may take time. But Congress has addressed this issue already by requiring the PTO to conduct reexaminations “with special dispatch.” 35 U.S.C. § 305; *see also* 37 C.F.R. § 1.550(a) (“All *ex parte* reexamination proceedings, including any appeals to the Board of Patent Appeals and Interferences, will be conducted with special dispatch within the Office.”); *Ethicon*, 849 F.2d at 1426 (concluding that “special dispatch” requires “unique, extraordinary, or accelerated movement”). Moreover, such concerns are “tempered by Defendants’ obvious angst that . . . continued litigation in this court at the present

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<sup>3</sup> Unlike Talecris, the defendants in *Cornerstone* had not filed an Answer, *see* 5:07-CV-00389-F, Exhibit I, at 3, but the mere filing of an Answer does not change the fact that this case remains “in the initial stages of the lawsuit,” *ASCII*, 844 F. Supp. at 1381.

time would be unnecessarily costly and duplicative” if the PTO rejects the claims of the patents-in-suit. *Cornerstone*, 5:07-CV-00389-F, Exhibit I, at 3. Talecris shares with the *Cornerstone* defendants the concerns over potentially unnecessary costs and duplication of effort, and, like those defendants, Talecris has not unduly delayed filing a reexamination petition or engaged in other dilatory tactics. *See id.*

Nor is this a case where time is of the essence. To the contrary, Plaintiffs delayed filing this lawsuit against Talecris for more than ten years after the first of the patents-in-suit was issued, even though Talecris and its predecessors have been continuously testing blood plasma during that entire period. Moreover, Plaintiffs have not sought a preliminary injunction, so damages, if any, accrued during the stay period would be sufficient to compensate them for any infringement.

Third, as *Cornerstone* found, a stay pending reexamination “will, at the very least simplify the issues and streamline the trial, thereby reducing the burden on, and preserving the resources of both the parties and the court.” *Id.* at 4. A stay would conserve this Court’s resources, as the PTO can resolve the validity issues in this case efficiently. Furthermore, Talecris has filed a counterclaim alleging that Plaintiffs’ lawsuit constitutes sham litigation, *see generally* Talecris’ Answer and Counterclaims [D.I. 16], and a stay would mitigate the harm to Talecris from this sham litigation.

As described above, the PTO already has concluded that the claims of applications related to the patents-in-suit are not patentable. The PTO merely must extend that conclusion to the claims of the patents-in-suit, which it has already determined are essentially the same for patentability purposes as the claims it rejected in the ’780 and ’484 applications. The reexaminations will result in one of three outcomes: the cancellation or modification of all of the

claims of the patents-in-suit, the cancellation or modification of fewer than all claims, or the affirmance of all claims. Talecris believes that reexaminations will result in the cancellation of all claims and the effective end of this litigation. Nonetheless, even if any claims of the patents-in-suit survive the reexaminations, a stay would greatly reduce the work by the parties and the Court in this case. For example, the issues in this case would be narrowed even if only some of the claims are cancelled or modified. Moreover, absent a stay, the Court might have to repeat claim construction and motions practice in light of the reexaminations. *See, e.g., Softview Computer Prods. Corp. v. Haworth, Inc.*, 2000 WL 1134471, Exhibit J, at \*3 (S.D.N.Y. Aug. 10, 2000). A stay pending the PTO's reexaminations would therefore be the most efficient method of resolving the dispute between Plaintiffs and Talecris.

### **CONCLUSION**

For the foregoing reasons, Talecris respectfully requests that a stay be entered pending completion of the reexaminations and related appeals.<sup>4</sup>

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<sup>4</sup> Plaintiffs may argue that a decision on whether to enter a stay should be delayed until the PTO formally grants reexamination. *See* 35 U.S.C. § 303(a) (requiring the PTO to respond within three months). As noted above, grant of the reexamination requests is almost certain. Given that defendants have raised substantial validity issues here, there is no reason to continue with the expense of litigation when Congress has provided for the PTO to address those validity issues. *See eSoft*, 505 F. Supp. 2d at 789 (entering a stay and directing the parties to “immediately advise the court of the PTO’s decision to grant or deny Defendant’s petition for reexamination”). In fact, courts have even entered stays to give a party “the opportunity to file an application for reexamination and/or reissuance.” *ASCH*, 844 F. Supp. at 1381.



Respectfully submitted this the 4th day of December, 2008.

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## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that he is an attorney at law licensed to practice in the State of North Carolina, is an attorney for Defendant Talecris Biotherapeutics, Inc. and is a person of such age and discretion as to be competent to serve process.

That on December 4, 2008 he served copies of the attached **MEMORANDUM IN SUPPORT OF DEFENDANT TALECRIS BIOTHERAPEUTICS, INC.'S MOTION TO STAY CASE PENDING REEXAMINATION** in the manner stated below.

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